



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,871	08/20/2003	Mary Anne Nelson	7205104	5206
52297 7590 03/01/2007 GONZALES PATENT SERVICES 4605 CONGRESS AVE. NW ALBUQUERQUE, NM 87114			EXAMINER FORMAN, BETTY J	
			ART UNIT	PAPER NUMBER
			1634	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/01/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/643,871

Applicant(s)

NELSON ET AL.

Examiner

BJ Forman

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 16-25, 30-35 and 103-148 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 16-25, 30-35 and 103-148 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1634

FINAL ACTION

Status of the Claims

1. This action is in response to papers filed 7 December 2006 in which claims 1-2, 4, 6, 8, 18 were amended, claims 9-15, 26-29, 36-102 were canceled and claims 103-148 were added. All of the amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 8 August 2006 are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. New grounds for rejection, necessitated by the amendments, are discussed.

Claims 1-8, 16-25, 30-35, 103-148 are under prosecution.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 103-148 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

New independent Claims 103 and 127 are drawn to exogenous tyrosine-tags and exogenous histidine tags. Applicant has not pointed to support in the specification. While the specification defines tags at terminal residues (e.g. ¶ 55-56), the specification does not teach or define exogenous tyrosine-tags or exogenous histidine tags as newly claimed.

Art Unit: 1634

Therefore, the specification does not convey to one skilled in the art that the inventors had possession of the claimed invention at the time the application was filed.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 127-133, 142-147 are rejected under 35 U.S.C. 102(e) as being anticipated by Hillenkamp (U.S. Patent No. 6,558,902, filed 7 May 1999).

Regarding Claim 127, Hillenkamp discloses a microarray comprising an inorganic thiolate amine treated substrate (Column 33, lines 48-67) a diazotized tether group bound to the substrate (Column 33, lines 35-38) at least one polypeptide covalently bound to the diazotized tether group (Column 33, lines 28-32) wherein the polypeptide is bound via a his-tag (Column 56, lines 12-23).

Regarding Claim 128, Hillenkamp discloses the microarray wherein the his-tag comprises at least one terminal histidine residue (Column 56, lines 12-23 and Column 63, line 60-Column 64, line 15).

Regarding Claim 129, Hillenkamp discloses the microarray wherein the polypeptide is covalently bound via a terminal his-tag (Column 56, lines 12-23 and Column 63, line 60-Column 64, line 15).

Art Unit: 1634

Regarding Claim 130, Hillenkamp discloses the microarray wherein the his-tag comprises 6 histidine residues (Column 56, lines 12-23 and Column 63, line 60-Column 64, line 15).

Regarding Claim 131, Hillenkamp discloses the microarray wherein polypeptide is bound at one of the his-tag to a diazotized support (Column 33, lines 28-67; Column 56, lines 12-23 and Column 63, line 60-Column 64, line 15).

Regarding Claim 132, Hillenkamp discloses the microarray wherein the his-tag comprises up to 20 histidine residues e.g. 6 histidine residues (Column 56, lines 12-23 and Column 63, line 60-Column 64, line 15).

Regarding Claim 133, Hillenkamp discloses the microarray wherein the polypeptide is covalently bound via a terminal his-tag (Column 56, lines 12-23 and Column 63, line 60-Column 64, line 15).

Regarding Claims 142-146, Hillenkamp discloses the microarray wherein the substrate comprises a noble metal, is coated with a noble metal, comprises gold, comprises silver, or comprise copper (Column 33, line 65-Column 34, line 40).

Regarding Claim 147, Hillenkamp discloses the microarray wherein the diazotized tether group comprises a thiolate i.e. diazo reacted with a thiol functionality (Column 33, lines 28-62).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1634

7. Claims 1-8, 16-25, 30-35, 103-148 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hillenkamp (U.S. Patent No. 6,558,902, filed 7 May 1999) and Clark (U.S. Patent No. 5,484,852, issued 16 January 1996).

Regarding Claims 1-8, 16-25, 30-35, 127-133, 142-148, Hillenkamp discloses a microarray comprising an inorganic thiolate amine treated substrate (Column 33, lines 48-67) a diazotized tether group bound to the substrate (Column 33, lines 35-38) at least one polypeptide covalently bound to the diazotized tether group (Column 33, lines 28-32) wherein the polypeptide is bound via a his-tag (Column 56, lines 12-23) wherein the his-tag comprises at least one terminal histidine residue (Column 56, lines 12-23 and Column 63, line 60-Column 64, line 15) wherein the polypeptide is covalently bound via a terminal his-tag (Column 56, lines 12-23 and Column 63, line 60-Column 64, line 15) wherein the his-tag comprises 6 histidine residues (Column 56, lines 12-23 and Column 63, line 60-Column 64, line 15) wherein the substrate comprises a noble metal, is coated with a noble metal, comprises gold, comprises silver, or comprise copper (Column 33, line 65-Column 34, line 40) and wherein the microarray comprises at least 2 different polypeptides and/or proteins (Column 31, line 62-Column 3, line 13 and Column 35, lines 25-28).

Clark discloses a similar microarray (i.e. solid support, Abstract) comprising a diazotized tether group bound to a substrate and at least one polypeptide covalently bound to the tether (Column 10, lines 5-24) wherein the microarray comprises a plurality of different polypeptides (Column 10, lines 20-22) wherein the substrate having a thickness of "approximately" 1mm (i.e. 100Å, Table 1 and Column 10, lines 7-8) wherein the tether group is a thiolate diazonium i.e. thiolate diazonium comprises p-diazoiodothiophenol salt (Column 5, lines 10-37). Clark further teaches the support wherein the protein is linked to the support via long or short bridge as known in the art and comprising poly amino acids (Column 5, lines 15-18, 38-48) but the reference does not teach specific amino acids e.g. histidine.

Art Unit: 1634

Regarding Claims 34-35, 125-126 and 147-148, Clark discloses a microarray (i.e. solid support, Abstract) comprising a diazotized tether group bound to a substrate and at least one polypeptide covalently bound to the tether (Column 10, lines 5-24). It is noted that the instant specification defines a microarray as "a device that employs the attachment of biomolecules, such as polypeptides, to a substrate." (§ 34). Clark further discloses the diazonium comprises p-diaxoinumthiophenol salt (Column 5, lines 10-37) and teaches the diazo group is linked via an oxy group, a silyl group or the like (Column 4, lines 23-27). This clearly suggests a siloxy diazonium group as claimed. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the teaching of Clark and to use a siloxy group to link the protein via the diazonium. One of ordinary skill in the art would have been motivated to do so based on the teachings of Clark (Column 4, lines 23-27).

Regarding Claims 16-25, 111-120 and 142-146, Clark discloses a microarray (i.e. solid support, Abstract) comprising a diazotized tether group bound to a substrate and at least one polypeptide covalently bound to the tether (Column 10, lines 5-24). It is noted that the instant specification defines a microarray as "a device that employs the attachment of biomolecules, such as polypeptides, to a substrate." (§ 34). Clark exemplifies a polystyrene microtiter plate (Column 10, lines 7-8) but suggests numerous other substrates and substrate forms (Column 2, lines 32-40). While Clark does not specifically teach the claimed substrates, they were well known and routinely practiced as microarray substrates at the time the claimed invention was made as taught by Hillenkamp who teaches the preferred microarray substrates as claimed (Column 33, line 65-Column 36, line 17). Hence, the claimed substrates were known and practiced as functional microarray substrates. Therefore one of ordinary skill in the art would have been motivated to use any one of the claimed substrates with a reasonable expectation of success. One of ordinary skill would have been motivated to use any one of the claimed substrates based on the preferred teachings of Hillenkamp and based on available materials and/or experimental design.

Art Unit: 1634

The courts have stated with regard to physical and chemical homologs that the greater the physical and chemical similarities between the claimed species and any species disclosed in the prior art, the greater the expectation that the claimed subject matter will function in an equivalent manner (see *Dillon*, 99 F.2d at 696, 16 USPQ2d at 1904).

While Hillenkamp teaches a silicon substrate a diazotized tether and a polypeptide tag e.g. his-tag, the reference does not specifically teach a substrate having an amine functional group for attaching a diazotized tether. However, as cited above, amine functional groups for attaching diazotized tethers were well known and routinely practiced in the art at the time the claimed invention was made as taught by Clark.

Clark teaches that diazotized substrates prepared using their method provides enhanced functionalization of the surface and higher levels of binding a wide variety of molecules and find "particular use for separations or high density packing of a moiety of interest" (Abstract and Column 2, lines 4-11). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the diazotized substrates of Clark to the substrate of Hillenkamp. One of ordinary skill in the art would have been motivated to do so for the expected benefits taught by Clark (Abstract and Column 2, lines 4-11).

8. Claims 103-126 and 135-141 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hillenkamp (U.S. Patent No. 6,558,902, filed 7 May 1999) and Clark (U.S. Patent No. 5,484,852, issued 16 January 1996) and further in view of Currell et al (J. Applied Polymer Sci, 1997, 66: 1433-1438).

Regarding Claim 103-126 and 135-141, Hillenkamp teaches polypeptides are immobilized via polypeptide linkers (Column 56, lines 11-23) and Clark teaches the polypeptide

Art Unit: 1634

immobilization via poly-amino acid linkers (Column 5, lines 45-47) but both are silent regarding amino acid linker being tyrosine.

However, covalent linkage of a protein to a solid support via a tyrosine tag at the terminus of the protein was well known in the art at the time the claimed invention was made as taught by Currell et al. Currell et al teach a similar protein immobilization wherein the protein is covalently linked to the support through a diazo-tyrosine bridge (Abstract). Currell et al further teach the immobilization wherein the diazo-tyrosine bridge attaches the protein at positions outside the active site (page 1437, first full paragraph) which suggests the coupling is also at internal histidine residues of the protein. Currell et al teach the immobilization is fast and stable under operating conditions without loss of function thereby providing a "choice" method of immobilization (page 1437, right column). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the diazo-tyrosine immobilization of Currell et al to the protein immobilization of Clark and Hillenkamp. One of ordinary skill in the art would have been motivated to do so based on the suggested polyaminoacid bridge of Clark and Hillenkamp. One would have been further motivated for the expected benefit of fast immobilization that is stable under operating conditions without loss of function thereby providing a "choice" method of immobilization as taught by Currell et al (page 1437, right column). It would have been further obvious to modify the polyaminoacid bridge of Clark by using a bridge containing 6 or 20 tyrosine residues based on the "short or long" bridge suggestion of Clark wherein the length of the bridge is selected based on intended use (Column 5, lines 15-18).

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1634

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

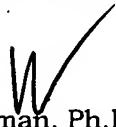
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your

Art Unit: 1634

application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
February 28, 2007